AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Please cancel claims 1 – 26 without prejudice and add the following new claims:

27. A physicochemically stable aqueous composition comprising clozapine in suspension.

28. A physicochemically stable aqueous composition according to claim 27 wherein the pH of the composition is maintained in the range of about 6 to about 11.

29. The composition according to claim 27 wherein the pH of the composition is maintained within the range of about 6 to about 11 using a buffer system.

30. The composition according to claim 27 wherein the buffer system is a sodium phosphate/sodium hydroxide buffer system.

31. The composition according to claim 27 wherein the pH is maintained in the range of from about 6 to about 8.

32. The composition according to claim 27 wherein the amount of clozapine in the composition is from about 0.1% to about 10% by weight based on the total volume of the composition.

33. The composition according to claim 27 further comprising a wetting agent.

34. The composition according to claim 27 comprising a wetting agent in an amount of between about 0.1% and about 15%.

35. The composition according to claim 27 comprising a wetting agent selected from any one or more of propylene glycol, glycerin, or polyethylene glycol.

36. The composition according to claim 27 wherein the composition includes a suspending agent and/or a preservative.

37. The composition according to claim 27 comprising a preservative selected from any one or more of methyl, propyl and butyl parabens.

38. The composition according to claim 27 wherein the composition includes: clozapine, glycerine, sodium dihydrogen phosphate dihydrate/NaOH buffer, xanthan gum, methyl paraben, propyl paraben, butyl paraben, and water.

39. A method for preparing a physicochemically stable aqueous composition including clozapine in suspension, the method comprising the step of controlling the pH of the formulation between about 6 and about 11.

40. The method according to claim 39 wherein the pH is controlled between 6 and 8.

41. The method according to claim 39 wherein the method further includes the addition of PVP.

42. A method of producing a physicochemically stable aqueous composition comprising clozapine in suspension comprising the following steps:

(a) stirring the clozapine with about three quarters of the propylene glycol ascribed to the batch;

(b) addition of the buffer salt (and optionally sweetening agents) dissolved in about half the volume of water ascribed to the batch with constant stirring;

(c) adjusting the pH value with the base component of the buffer with mixing;

(d) addition of the preservatives dissolved in the remaining propylene glycol;

(e) slow addition of the suspending agent with continuous stirring until the mixture thickens; and,

(f) further diluting the suspension with water to the desired end-volume.

43. A method for producing a physicochemically stable aqueous composition comprising clozapine in suspension comprising the following steps:

(a) stirring the clozapine with about three quarters of the glycerine ascribed to the batch;

(b) addition of the buffer salt (and optionally sweetening agents) dissolved in about half the volume of water ascribed to the batch with constant stirring;

(c) adjusting the pH value with the base component of the buffer with mixing;

(d) addition of the preservatives dissolved in a small volume of water;

(e) slow addition of the suspending agent wetted with the remaining glycerine with continuous stirring until the mixture thickens; and,

(f) further diluting the suspension with water to the desired end-volume.

44. The method according to claim 42 wherein PVP is added as an aqueous solution following addition of the suspending agent.

45. The method according to claim 43 wherein PVP is added as an aqueous solution following addition of the suspending agent.